

Serial No.: 10/594,453
Attorney Docket No.: LNK-019
DRAFT After Final Response of June 16, 2009

REMARKS

Pursuant to the entry of the instant amendment, claims 1, 16, 19, 21, and 23 are canceled and claims 2, 4-14, 17 and 18 are amended, leaving at issue claims 2, 4-15, 17, 18, 20, 22, and 24. In particular, in an effort to expedite prosecution, Applicants herewith have amended the sole remaining independent claim – claim 2 – to utilize the closed language (“*consisting of*”) as opposed to the previously iterated open language (“*comprising*”). Applicants have further amended claim 2 to include the limitations of dependent claim 16 (i.e., further treating the composition obtained step (ii) to yield at least one purified coagulation factor), now cancelled. Applicants respectfully submit that these amendments render moot the outstanding claim rejections and place the present application in condition for allowance. Further to this position, Applicants submit the following remarks:

Claim Rejections under 35 U.S.C. § 103

In the outstanding Final Office Action, the Examiner finally rejected claims 1, 3-5, and 10-11 under 35 U.S.C. § 103(a) as being obvious over Zykova et al. Applicants note that neither claim 2 nor claim 16 was included in this rejection. Accordingly, this rejection is rendered moot by the cancellation of independent claim 1.

The Examiner further rejected claims 1-24 under 35 U.S.C. § 103(a) as being obvious over Wallace et al., alone (claims 1-14, 16, and 18-24) or in combination with Burnouf Radosevich et al. (claims 15 and 17). Applicants respectfully submit that the above noted amendments to independent claim 2 serve to distinguish the inventive process from that of Wallace, alone or as modified by Burnouf Radosevich. In particular, Applicants respectfully submit that the closed language of claim 2 precludes the application of the Wallace reference, which describes a complex, multi-step process for the preparation of fibronectin and fibronectin substitutes from an acid-chill precipitate. As shown in Figure 2, the Wallace method includes several distinct steps, in addition to those recited in claim 2 as amended herewith, including multiple centrifugation steps to obtain a purified fibronectin substitute precipitate and further cooling steps to precipitate remaining fibronectin, though capturing at most 60% of the fibronectin present in the original plasma fraction. In contrast, the pending claims relate to a

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simple one-step titration process that results in the direct quantitative separation of fibronectin from a plasma solution to yield a purified coagulation factor, more particularly a von Willebrand factor (vWF), as well as the high yield recovery of 70 to 99%, more preferably at least 90% of the fibronectin present in the plasma fraction. By omitting the steps required by Wallace and by (1) adding the acidic component(s) over a certain period of time, e.g., dropwise (see p. 5, third paragraph of the instant specification); and (2) keeping the plasma fraction moving or mixed, e.g., by stirring after the pH adjustment (see p. 5, fourth paragraph). Applicants are able to provide very efficient precipitation of fibronectin.

An even better precipitation can be achieved by (3) carrying out steps (i) and (ii) at room temperature. To that end, Applicants direct the Examiner's attention to Example 1 of the instant specification and in particular the data presented in Table 2 which clearly demonstrate that fibronectin removal is most efficient at 20 °C, as compared to 4 °C (i.e., Wallace et al.) and 35 °C. Applicants respectfully submit that the unexpected superior results obtained by Applicants could not have been predicted by one of ordinary skill in the art, particularly in view of the teachings of Wallace et al. that clearly suggest towards acid-chill procedures, and thus serve as further indicia of non-obviousness.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the outstanding rejection of claims 1-24 as being obvious over the prior art of record in view of the amendments and remarks presented herewith.

CONCLUSION

In view of the above, Applicant respectfully submits that claims 2, 4-15, 17, 18, 20, 22, and 24 are in condition for allowance and respectfully request an early notification of such.

The outstanding Final Office Action set a three-month shortened statutory period for response, response being due on or before **June 12, 2009**. Accordingly, Applicant respectfully submits that this response is timely and no fee is required. However, in the event that further fees are required to enter the instant response and/or maintain the pendency of this application, the Commissioner is authorized to charge such fees to our Deposit Account No. 50-2101.

If the Examiner has any questions or concerns regarding this communication, he is invited to contact the undersigned.

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Respectfully submitted,

Date: June 16, 2009

By: /DRAFT?

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